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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,413	12/12/2003	Steven F. Bolling	ORQIS.018A	2138

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

NOTIFICATION DATE	DELIVERY MODE
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08/08/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No. 10/735,413	Applicant(s) BOLLING ET AL.	
	Examiner CHRISTOPHER D. KOHARSKI	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/11/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-13,20-22,41 and 46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-13, 20-22, 41 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/11/2008 has been entered.

Response to Amendment

Examiner acknowledges the reply filed 4/11/2008 in which claims 1, 6 and 20 were amended. Currently claims 1, 3-13, 20-22, 41 and 46 are pending in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-10, 20-22, 41 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Liprie (USPN5,947,924). Liprie discloses a dilation/centering catheter used for treatment of stenosis.

Regarding claims 1, 3-10, 20-22, 41 and 46, Liprie discloses a perfusion cannula (Figures 10-11) system capable of directing blood through the vasculature of a patient,

comprising: a cannula body (12) comprising a proximal end, a distal end, and at least one lumen (13) extending therebetween; and a balloon (41) located on an exterior and coupled to a surface of the cannula body, such that when the balloon is deployed a recess is defined between an outside surface of the balloon and an outside surface of the cannula body; and whereby space the recess is adapted to permit blood flow past the cannula body along a vessel wall when the cannula body resides in the patient, wherein the balloon comprises a first balloon (41 top portion) and further comprising at least a second (41, bottom portion) balloon spaced radially from the first balloon, further comprising a second lumen (22), wherein the deploying means comprises an inflation lumen (32, 34, Figures 1-12).

Claim Rejections - 35 USC § 102

Claims 1, 4-10, 20-22 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Brill (USPN5,395,333). Brill discloses a multi-lobed support balloon catheter with perfusion.

Regarding claims 1, 4-10, 20-22 and 46, Brill discloses a perfusion cannula (10) (Figures 1-2) system capable of directing blood through the vasculature of a patient, comprising: a cannula body (14) comprising a proximal end, a distal end, and at least one lumen (38) extending therebetween; and a balloon (32A-G) located on an exterior and coupled to a surface of the cannula body (34), such that when the balloon (32A-G) is deployed a recess is defined between an outside surface of the balloon and an outside surface of the cannula body (34); and whereby space the recess is adapted to permit blood flow past the cannula body along a vessel wall when the cannula body

resides in the patient, wherein the balloon comprises a first balloon (32A-G) and further comprising at least a second (32A-G) balloon spaced radially from the first balloon, wherein the deploying means comprises an inflation lumen (20, Figures 1-5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liprie (USPN5,947,924) (or Brill (USPN5,395,333) in view of Aigner (USPN4,540,402). Liprie (or Brill) meets the claim limitations as described above except for a second lumen.

However, Aigner teaches a double perfusion catheter.

Regarding claims 11-13, Aigner teaches a perfusion catheter (1) with a first (6) and second (5) lumen for controlled location perfusion (Figures 1 and 4).

At the time of the invention, it would have been obvious to add a second lumen of a shorter distance in order allow for additional perfusion and allow for perfusion in isolated areas. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Aigner (cols 1-2).

Response to Arguments

Applicant's arguments with respect to claims 1, 3-13, 20-22, 41 and 46 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 7/31/2008

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763